REMARKS

Claims 67 and 124 were previously pending in this application. Applicant has not made any amendments to the claims and accordingly, no new matter has been added.

Objection to the Specification

The Examiner objected to the specification because there are sequences on page 78 of the specification that are not identified by SEQ ID NOs. Applicant has amended the paragraph to add the appropriate SEQ ID NOs. Accordingly, withdrawal of the objection is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 67 and 124 under 35 U.S.C. §112, first paragraph, as not enabled. The Examiner asserts that the specification "has not set forth reaction conditions and starting materials that would enable the use of the claimed polynucleotides in a method that would satisfy the requirements of 35 U.S.C. 101." (Office Action at page 3). Quoting from Genentech v. Novo Nordisk A/S, 42 USPQ2d 1001, the Examiner emphasized the following passages, which presumably are meant to indicate the essence of the enablement rejection within the lengthy quotes: "Tossing out the mere germ of an idea does not constitute enabling disclosure" and "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." (Office Action at page 4).

In particular, the Examiner deems that the specification has not enabled the use of the claimed nucleic acids. Applicant respectfully disagrees.

Applicant's specification does much more than "toss out the mere germ of an idea" and Applicant does not rely on the knowledge of the skilled person to "supply the novel aspects" of the invention.

The specification describes the use of autologous antibody screening method (SEREX) to identify cancer associated antigens. The claimed sequences are part of "NA Group 1", which is described in the section of the Detailed Description entitled "Nucleic Acid Sequences". SEQ ID NO:681 is one of the antigens disclosed in the sequence listing, and therefore is a part of the invention explicitly disclosed by Applicant in the specification.

The fourth paragraph of the Summary of the Invention section makes it clear that "the invention has in vivo and in vitro uses, including for therapeutic, diagnostic, monitoring and research purposes." In the third paragraph of the Summary of the Invention, the specification states that "a single gene, a single protein encoded by a gene, a single functional fragment thereof, a single antibody thereto, etc. can be used in methods and products of the invention". The Summary of the Invention section proceeds to describe a variety of methods in which the sequences of the invention (including SEQ ID NO:681) can be used by those skilled in the art. With respect to fragments of SEQ ID NO:681, the specification provides a number of uses that the skilled person is highly familiar with and routinely practices, including: as hybridization probes, as PCR primers (including as part of kits of primers). Still another use is the inclusion in nucleic acids encoding a series of epitopes, known as "polytopes". In addition, the specification describes the use of the nucleic acid sequences in producing polypeptides and peptides, which each have their own uses described in the specification.

The specification thus describes a number of uses of the full length sequence and fragments thereof, which uses are well-known to, and routinely practiced by, those of skill in the art. Having provided the sequences and described various uses, Applicant has provided much more than "the mere germ of an idea"; the uses described in the specification represent fully developed uses that are readily implemented by skilled persons. The person of skill need not supply any novel aspect for these uses; because Applicant has provided the sequences and

described the uses, one of ordinary skill in the art is enabled to practice the full scope of claimed invention (the nucleic acid molecules).

The Examiner's statement on page 4 of the Office Action that there is a "general absence of a reproducible method for the use of the claimed nucleic acid[s]" is therefore erroneous.

In addition, the Examiner added that, because the specification does not set forth "any method for the use of the polynucleotide or its fragments, the specification has not also set forth the best mode contemplated by applicant." (Office Action at page 4). Applicant respectfully disagrees. For the reasons noted above, Applicant has provided a number of methods for using the claimed nucleic acid molecules.

Moreover, the standard for meeting the best mode requirement is that the specification set forth the best mode for practicing the invention that is known to the Applicant at the time that the application is filed. To the extent that there was a best mode known to Applicant, this has been set forth in the specification. Therefore, Applicant clearly has satisfied the best mode requirement.

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of the claims made under 35 U.S.C. § 112, first paragraph, for lack of enablement and best mode.

Rejection Under 35 U.S.C. § 101

The Examiner rejected claims 67 and 124 under 35 U.S.C. §101, as not supported by either a specific, substantial and credible utility or a well-established utility.

Applicant's description in the specification of a number of uses for SEQ ID NO:681 and fragments thereof was set forth above in response to the enablement rejection. These same examples of uses of the claimed nucleic acids provide at least a well-established utility.

Applicant's specification provided a large number of sequences that all were identified using autologous antibody screening (SEREX) methodology, and thus share certain uses, as described above. Due to the number of sequences, it would have been inefficient, duplicative and unreasonably burdensome for Applicant to individually list each sequence and reiterate for each sequence the possible methods that the sequence could be used in. For that reason, Applicant described the identified sequences using "NA Group" nomenclature. The sequences could be grouped in this way because the sequences all were isolated in the same way (using SEREX) and thus all shared certain properties, e.g., encoding cancer associated antigen precursors, and accordingly, certain uses.

Moreover, Applicant notes that the claimed fragments have utility as described in the specification, for example, as follows. At page 20, lines 20-30, Applicant described the utility of fragments as probes in Southern and Northern blot assays, as primers for nucleic acid amplification, e.g., PCR, to produce fragments of cancer antigens (which are described in the specification as useful to induce an immune response, and in immunoassays), and as antisense molecules to inhibit expression. At page 87, line 32 – page 88, line 1, Applicant described the utility of fragments to identify the region of a gene that encodes a peptide that induces an immune response. At page 14, lines 7-9, Applicant described fragments as encoding a portion of a polypeptide that binds an MHC molecule.

Each of the uses set forth in the specification is specific, credible and well-established. Thus, it is clear that Applicant identified that each of the sequences provided in the specification could be used in the recited methods (and other uses). Accordingly, the claimed sequences are supported in the specification as having specific, credible and well-known utility.

Therefore, Applicant's specification does indeed provide utility for the claimed nucleic acid sequences. Accordingly, Applicant respectfully requests withdrawal of the rejection of the claims made under 35 U.S.C. § 101.

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 67 and 124 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Regarding claim 67, the Examiner indicated that the specification does not adequately describe fragments of SEQ ID NO:681 that are at least 24 nucleotides long. The Examiner also stated that "the specification's silence as to which fragments are useful is not to be found." (*sic*, Office Action at page 6). The Examiner also asserted that Applicant attempts to satisfy the written description requirement "through obviousness". (Office Action at page 6). Applicant respectfully disagrees for the following reasons.

According to the legal standard of written description, the specification must describe the claimed invention such that one of ordinary skill in the art can recognize that Applicant possessed the claimed invention. University of Rochester v. G.D. Searle & Co. 68 USPQ2d 1424, 1428 (Fed Cir. 2004)("Rochester"). Applicant provided the sequence of SEQ ID NO:681 and quite clearly described that all fragments of this nucleotide sequence at least 24 nucleotides in length were encompassed in the invention. Persons skilled in molecular biology would understand from this description that Applicant has provided a full length sequence and fragments of the sequence that are at least 24 nucleotides in length. The description of the fragments by Applicant is conventional in molecular biology. Thus anyone skilled in the art would recognize that Applicant has invented the claimed subject matter. Accordingly, Applicant has done exactly what the law requires, and no resort to obviousness is needed since a full description of the claimed fragments is provided.

The Rochester case also discussed that a description that only renders the claimed invention obvious is not an adequate description. The court was addressing the description of the Rochester inventors as it related to the claimed invention; in particular, the Rochester specification did not describe any compounds that could be used to inhibit the Cox-2 enzyme. In contrast, Applicant's specification provides the nucleotide sequence of SEQ ID NO:681 and

describes that the invention includes fragments of this nucleotide sequence. The skilled person is thereby provided a description that clearly conveys that the Applicant invented the claimed fragments. A rote listing of each individual fragment of SEQ ID NO:681 that is 24 or more nucleotides long is simply not required (nor is it conventional in the art), just as a listing of degenerate sequences that encode an amino acid sequence is not required, to satisfy the written description requirement.

In discussing the written description requirement, the courts have indicated that various means can be used to describe the claimed invention, including structures, formulas, words, etc. In the instant specification, the fragments are clearly and adequately described by a combination of a formula or structure (the nucleotide sequence) coupled with words that describe that fragments are part of the claimed invention. The description of the invention does not rely on obviousness for its description; it is fully described in a manner that indicates to one of ordinary skill in the art that Applicant possessed the invention.

Regarding claim 124, the Examiner indicated that the specification does not teach the coding region of SEQ ID NO:681, and thus one of ordinary skill in the art would not be able to identify degenerate sequences corresponding to SEQ ID NO:681. Applicant respectfully disagrees.

The written description requirement does not mandate an explicit listing of each possible degenerate sequence within the claimed invention. All that is required is that the skilled person would recognize that the inventor possessed or invented the claimed invention. In the instant case, the possession of degenerate sequences of SEQ ID NO:681 is sufficient to convey possession of the claimed invention.

The SEREX method used to isolate SEQ ID NO:681 necessarily means that the cloned (and claimed) sequence must have at least one coding region/sequence. See the Background of the Invention section of the specification, which states: "According to this approach [SEREX], autologous antisera are used to identify immunogenic protein antigens expressed in cancer cells by screening expression libraries constructed from tumor cell cDNA." Having a coding region

necessarily means that the sequence has degeneracy due to redundancy of the genetic code. Since anyone skilled in the art would recognize that this must be so, the skilled person must also recognize that Applicant was in possession of, i.e., has invented, the claimed invention.

Moreover, even in an abstract sense, without reference to any coding region, the skilled person would recognize that Applicant invented the claimed invention. As noted above, because the claimed nucleic acid molecule must have a coding region, the skilled artisan will understand that the claimed molecule must also have degenerate equivalent sequences. Because Applicant's specification described these molecules, Applicant adequately conveyed to the skilled person possession of the degenerate sequences embraced by claim 124 as required for written description.

For the foregoing reasons, the description does provide an adequate written description of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection of the claims made under 35 U.S.C. § 112, first paragraph, for lack of an adequate written description.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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